

## REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

### Personal Interview

Applicant and the undersigned wish to thank Mr. Thaler and Ms. Houston for the courteous and productive interview conducted on 3 April 2006 with the undersigned's representative, Mr. Adam Cermak. Because Applicant was not relieved of the duty under 37 C.F.R. § 1.33(b) of providing a summary of the arguments presented during that interview, Applicant provides the following comments.

Only two topics were covered during the interview: the rejection under 35 U.S.C. § 112, first paragraph; and the differences between the devices described in U.S. Patent No. 5,922,020, issued to Klein *et al.* ("Klein"), and the devices described in this application.

Mr. Cermak began by suggesting that the descriptions offered in the Office Action of the alleged failings of the claims under section 112, first paragraph, appeared to indicate that Ms. Houston's opinion was better stated that the claims were not supported by an adequate written description of the invention. Mr. Cermak also suggested that, by back-inserting the subject matters literally recited in the several claims into the specification, both the objection to the specification and the rejection under section 112, first paragraph, could be obviated. Mr. Thaler concurred, indicating that such amendments would likely remove these objections and rejections.

Mr. Cermak then explained one of the fundamental differences between the devices of *Klein* and those of this application. With reference to Fig. 7A of *Klein* and the exemplary embodiments illustrated in Figs. 3e and 9b of this

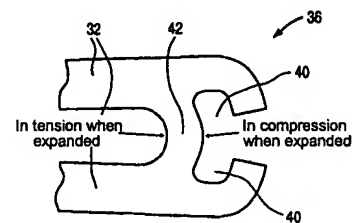


FIG. 7A

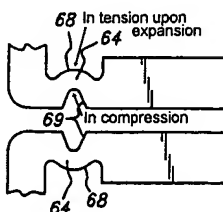


FIG. 3e

application, Mr. Cermak explained that *Klein's* hinges 36 are oriented opposite to those of this application, with significant performance differences as a result. As can be readily seen in Fig. 7A of *Klein*, reproduced herein (with annotations, and with reference numeral 44

removed for clarity), when the stent expands the longer surface of the hinge (on the right side in Fig. 7A) is in compression, while the shorter surface of the hinge (on the left side in Fig. 7A) is in tension. It was explained during the interview, exactly the opposite to *Klein*, that hinges of the present invention, such as the exemplary hinge illustrated in Fig. 3e of this application (a portion of which is also reproduced herein, in annotated form) have a longer surface that is in tension during expansion, and a shorter surface that is in compression. A result of the claimed hinge configuration, as compared to that of *Klein*, is that the claimed hinges are able to generate much more plastic deformation for a set amount of expansion of the device (e.g., as expressed as a percentage of a complete total expansion of the device) which, as explained in great depth and detail in this specification, can greatly assist in reducing elastic recoil during crimping and permits advantageous performance of the stent. The configuration of *Klein*'s hinges, on the other hand require compression of the longer side of the hinge, and tension of the shorter side.

Mr. Thaler and Ms. Houston appreciated this distinction, and encouraged Mr. Cermak to submit claims that included it.

Ms. Houston lastly indicated that there was some confusion over the subject matter that is recited in Claim 38, and asked that it be clarified.

### **Objection to the Specification**

In the Office Action, at page 2, the specification was objected to because it allegedly does not provide antecedence for subject matter, according to the Office Action, recited in Claims 28 and 42: "wherein the hinge length is smaller than the hinge thickness". Applicant respectfully requests reconsideration of this objection

The Office Action has misquoted the language from Claims 28 and 42, likely resulting in this objection. In fact, Claims 28 and 42 recited: "wherein the hinge width is smaller than the hinge thickness". Antecedence for this subject matter can be found throughout this specification, for example, at paragraph [0070] (in the published application).

For at least the foregoing reason, Applicant respectfully submits that the specification includes antecedence for the claimed subject matter, and therefore respectfully requests withdrawal of the objection thereto.

### **Objection to the Claims**

At page 2 of the Office Action, Claims 33, 34, 47, 48, and 55 were objected to because they allegedly included insufficient antecedence for specific terms. Applicant respectfully requests reconsideration of this objection.

By way of the foregoing amendments, the terms 'struts' have been replaced with the terms 'beams' to provide better consistency throughout the claims; withdrawal of the objections to the claims is therefore respectfully requested.

### **Rejection under 35 U.S.C. § 112, first paragraph**

In the Office Action, beginning at page 2, Claims 29, 30, 32-34, 43, 44, 46-48, and 53-55 were rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matters that allegedly failed to be supported by an enabling specification. Applicant respectfully requests reconsideration of this rejection.

As discussed above and during the personal interview, the back insertion of the specific language from some of the claims into the specification would obviate these rejections under section 112, first paragraph. By way of the foregoing amendments, such amendments have been made.

For at least the foregoing reasons, Applicant respectfully submits that Claims 29, 30, 32-34, 43, 44, 46-48, and 53-55 fully comply with 35 U.S.C. § 112, first paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

### **Rejection under 35 U.S.C. § 112, second paragraph**

In the Office Action, beginning at page 3, Claims 33, 47, and 55 were rejected under 35 U.S.C. § 112, second paragraph, as reciting subject matters that allegedly are indefinite. Applicant respectfully requests reconsideration of this rejection.

While Applicant strongly believes that the recitation of a 'cross-sectional area', in the context of this application, would be immediately understood by the ordinarily skilled artisan upon a full and fair reading of this application, in an effort to advance prosecution, Applicant has amended the phrases to recite that it is the cross-sectional areas of the beams and hinges, orthogonal to their lengths, that are recited.

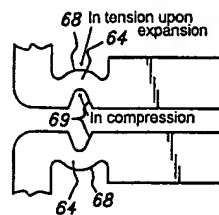
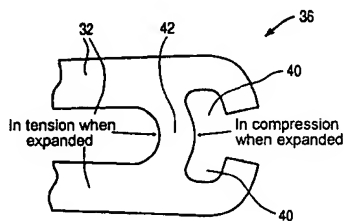
For at least the foregoing reasons, Applicant respectfully submits that Claims 33, 47, and 55 fully comply with 35 U.S.C. § 112, second paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

### Rejection under 35 U.S.C. § 102

In the Office Action, beginning at page 6, Claims 27, 30, 32-34, 36-41, 44, 46-48, and 50-55 were rejected under 35 U.S.C. § 102, as reciting subject matters that allegedly are anticipated by *Klein*. Applicant respectfully requests reconsideration of this rejection.

As discussed at length, both above and during the personal interview of 3 April 2006, among the numerous differences between the devices described and claimed in this application and those of *Klein*, is the orientation of the hinges and their stress-strain experiences during expansion of the devices.

Claim 27 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of ductile hinges connecting a plurality of beams together in a substantially cylindrical device, each hinge defining a width, a thickness, and a length, wherein the hinge width is smaller than the beam width such that as the device is expanded from a first diameter to a second diameter the ductile hinges experience plastic deformation while the beams are not plastically deformed, each of the ductile hinges being in the shape of a curved beam along said hinge length and having a first arcuate surface and a second arcuate surface, wherein the second arcuate surface is longer than the first arcuate surface, the curved beams of the hinges being positioned such that during expansion tensile strain is distributed along the second arcuate surface.



As discussed in depth above, *Klein* has hinge regions 36 which have opposing surfaces that are oriented oppositely to those recited in the combinations of the pending claims. That is, when *Klein*'s device is expanded, the longer side of *Klein*'s hinge is compressed and the shorter side is in tension, opposite to the claimed combinations. Accordingly, *Klein* fails to disclose or describe each and every element as recited in the combinations of the pending claims.

Claim 38 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of ductile hinges connecting the plurality of beams together in the substantially cylindrical device, each hinge defining a hinge width, wherein the hinge width is smaller than a beam width such that as the device is expanded from the first diameter to the second diameter the ductile hinges experience plastic deformation while the beams are not plastically deformed, the ductile hinges being asymmetrically configured to reach a predetermined strain level upon a first percentage of expansion and to reach the predetermined strain level upon a second percentage of compression, wherein the first percentage is larger than the second percentage.

Claim 38 describes in another way some of the differences between *Klein* and the present invention. Claim 38 describes a strain behavior of the hinges when the device is expanded a percentage of a initial diameter of the device, as compared to when the device is compressed a percentage of the initial diameter of the device. This behavior may be illustrated by way of non-limiting example, which has been created merely for illustration and does represent the actual performance of the device. One example of a stent meeting Claim 38 would includes a stent where -- when the device is expanded by 20% of the initial diameter, the highest strain achieved in the hinge is the same as when the device is compressed a smaller amount, e.g., 10%. This comes as one result of the asymmetric configuration of the hinges relative to the bending moments that are applied to the hinges when the device is expanded and compressed.

As discussed in the present specification with reference to Fig. 6, and as well understood by the ordinarily skilled artisan, the percentages of expansion and compression to achieve the same maximum strain for a straight beam would be equal, i.e. whether you apply a force upward or downward on the straight beam of Fig. 6 the same max strain will result. In contrast, as described in Claim 38, one has to expand the device more than to compress it, to achieve the same predetermined strain.

For a curved hinge such as *Klein*'s configuration, would be exactly the opposite, *i.e.*, one would have to compress the device more than expand it, to achieve the same maximum strain. Thus, a result of *Klein*'s configuration of hinges is that, when *Klein*'s hinges reach a predetermined strain level upon a first percentage of expansion and reach the predetermined strain level upon a second percentage of compression, the first percentage is smaller than the second percentage. Accordingly, *Klein* fails to disclose or describe each and every element as recited in the combinations of the pending claims.

Claim 50 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of ductile hinges connecting a plurality of beams together in a substantially cylindrical device, each hinge defining a hinge width and having first and second side surfaces, wherein the hinge width is smaller than a beam width such that as the device is expanded from the first diameter to the second diameter the ductile hinges experience plastic deformation while the beams are not plastically deformed, the ductile hinges being asymmetrically configured with a first side surface placed in compression during expansion of the device and a second side surface placed in tension during expansion of the device, wherein the first side surface has a length smaller than a length of the second side surface.

As discussed in depth above, *Klein* has hinge regions 36 which have opposing surfaces that are oriented oppositely to those recited in the combinations of the pending claims. That is, when *Klein*'s device is expanded, the longer side of *Klein*'s hinge is compressed and the shorter side is in tension, opposite to the claimed combinations. Accordingly, *Klein* fails to disclose or describe each and every element as recited in the combinations of the pending claims.

Applicant notes that, while some amendments have been made to independent claims 37, 38, and 50, none of them relate to the patentability of the claims, and instead are merely editorial and stylistic in nature.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 27, 30, 32-34, 36-41, 44, 46-48, and 50-55 are not anticipated by *Klein*, are therefore not unpatentable under 35 U.S.C. § 102, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 102.

**Rejection under 35 U.S.C. § 103(a)**

In the Office Action, beginning at page 7, Claims 28, 29, 31, 35, 42, 43, 45, 49, and 56 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over the disclosure of *Klein* alone, and in view of the disclosure of U.S. Patent No. 5,722,979, issued to Kusleika, or the disclosure of U.S. Patent No. 4,994,071, issued to MacGregor. Applicant respectfully requests reconsideration of these rejections.

Neither *Klein* itself, *Kusleika*, nor *MacGregor* makes up for the deficiencies of *Klein* with respect to the subject matters of the pending claims. That is, assuming *arguendo* that the routineer in the art would somewhere find motivation to modify *Klein* in the manner alleged in the Office Action to be obvious, the resulting hypothetical constructs would still not include each and every limitation recited in the combinations of the pending claims.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 28, 29, 31, 35, 42, 43, 45, 49, and 56, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).

**Obviousness-type Double Patenting Rejection**

In the Office Action, beginning at page 4, many of the claims were rejected under the judicially-created doctrine of obviousness-type double patenting as reciting subject matters that are allegedly not separately patentable over the subject matters recited in three of Applicant's prior U.S. patents and one co-pending application, as follows:

- (1) Claims 27-33, 35-47, and 49-56 over Claims 1-3, 5, 10-23, 25, and 26 of U.S. Patent No. 6,241,762;
- (2) Claims 27, 38, and 50 over Claims 1, 4, 7, and 11 of U.S. Patent No. 6,293,967 (" '967 patent"), in view of *Klein*;
- (3) Claims 27, 38, and 50 over Claims 1, 6, 11, and 16 of U.S. Patent No. 6,562,065, in view of *Klein*; and

(4) Claims 27-29, 31, 33-42, 44, 45, 47-50, 53, 55, and 56 over Claims 27 and 30-41 of pending U.S. application number 11/126,850 (“ ‘850 application”).

Applicant respectfully requests reconsideration of these rejections.

Concerning items (1) and (3), Applicant files, concurrently herewith, Terminal Disclaimers over these two U.S. patents. Accordingly, these rejections are now moot.

Concerning item (2), Applicant respectfully submits that the rejection is plainly erroneous, and should be withdrawn. More specifically, the Office Action states:

The patent discloses all of the limitations in the claims except for the ductile hinges being in the shape of a curved beam having first and second arcuate surfaces facing the same direction with the second arcuate surface being longer than the first. Klein discloses the limitations that are missing from the patent.

M.P.E.P. § 804(II)(B)(i) sets forth the minimum requirements for an obviousness-type double patenting rejection made in an Office Action:

Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and content of a patent claim relative to a claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

The conclusion of obviousness-type double patenting is made in light of these factual determinations.

Any obviousness-type double patenting rejection should make clear:

- (A) The differences between the inventions defined by the conflicting claims - a claim in the patent compared to a claim in the application; and
- (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent.



The Office Action's rejection over the '967 *patent* plainly fails to meet these bare minimums. The Office Action does not even attempt to compare the claims of the '967 *patent* to the subject matters recited in the pending claims, instead pointing to what the '967 *patent* discloses. At least this deficiency renders the rejections fatally flawed.

Furthermore, even if the Office Action had included a proper analysis, including a comparison of the claims' subject matters, and assuming *arguendo* that the ordinarily skilled artisan would somewhere find motivation to look to *Klein* to supply some feature not claimed in the '967 *patent*, the resulting hypothetical<sup>o</sup> construct would still not include each and every limitation recited in the combinations of the pending claims, for at least the same reasons as presented above with respect to *Klein* and the rejections under sections 102, 103.

Concerning item (4) above, Applicant also respectfully submits that the rejection is plainly erroneous, and should be withdrawn. More specifically, the Office Action states: "[the claims] are not patentably distinct because they are merely using synonymous language to claim the same limitations." Applicant respectfully disagrees. Among the 13 claims in the copending '850 *application* over which the Office Action alleges that obviousness-type double-patenting may exist, only two (Claims 32, 37) even mention that the 'ductile hinges are curved prismatic beams', and does not at all indicate the orientations of such curved prismatic beams, *e.g.*, which portions are in tension and compression during expansion of the device, or that the ductile hinges are asymmetrically configured with a first side surface placed in compression during expansion of the device and a second side surface placed in tension during expansion of the device, wherein the first side surface has a length smaller than a length of the second side surface. The Office Action fails to even attempt to make up for these gaps between the subject matters recited in the claims of this application and those of the '850 *application* and, therefore, fails to make out a *prima facie* case.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of the pending claims are separately patentable over the subject matters of the claims in Applicant's prior patents and co-pending application, and therefore respectfully requests withdrawal of the rejections thereof.

### **New Claims**

New Claims 57-62 have been added. Claim 57, the sole new independent claim, relates to an expandable medical device having a combination of limitations including, *inter alia*, a plurality of ductile hinges formed between a elongated struts, the ductile hinges allowing a cylindrical tube to be expanded or compressed from a first diameter to a second diameter by deformation of the ductile hinges, wherein the ductile hinges are asymmetrically configured to reach a predetermined strain level upon a first percentage of expansion and to reach the predetermined strain level upon a second percentage of compression, the first percentage being larger than the second percentage, and a plurality of holes formed in the elongated struts for containing a beneficial agent.

For at least the same reasons presented above, Applicant respectfully submits that the none of the prior art discloses, describes, or fairly suggests the subject matters of Claims 57-62. Applicant therefore respectfully requests an early indication of the allowability thereof.

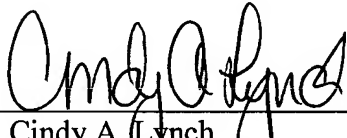
### **Conclusion**

Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of this patent application is therefore respectfully solicited.

If the patent examiner believes that a telephone conference with the undersigned would expedite passage of this patent application to issue, they are invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-3100.

Respectfully submitted,  
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